smokers seek adequate doses of nicotine to satisfy dependence and will compensate to achieve those doses when given a low-nicotine cigarette.[687] The cigarette industry, in contrast, denies that smokers compensate for nicotine to any significant extent. It is not credible that the industry would have accepted and acted on outsiders' recommendations while rejecting the fundamental premises on which the recommendations were based. Moreover, the Surgeon General, while suggesting that cigarettes with a lower tar-to-nicotine ratio should be investigated, specifically cautioned against achieving this goal through strategies that reduced tar while maintaining a normal nicotine yield:

> [F]actors of "smoker compensation" must be considered in the evaluation of lower "tar" and nicotine cigarettes. Filtered, lower "tar" and nicotine cigarettes that are less vulnerable to increasing the smoke and nicotine deliveries are needed. . . . Attempting to minimize smoker compensation by selectively reducing "tar" and other smoke compounds while maintaining nicotine yield may carry serious disadvantages. First, maintaining nicotine delivery may reinfore physiologic habituation, and interfere with smoking cessation attempts. Second, nicotine gives rise to the tobacco-specific carcinogenic N-nitrosamines . . . Finally, nicotine is suspected to be a major smoke constituent correlated with the increased risk of cardiovascular disease among cigarette smokers.[688]

Accordingly, the evidence establishes that the industry researched and developed methods to increase relative nicotine deliveries while decreasing tar deliveries for a commercial purpose—to ensure that cigarettes provide pharmacologically satisfying doses of nicotine.

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[687] *See, e.g.*, Russell MAH, *et al.*, Comparison of effect on tobacco consumption and carbon monoxide absorption of changing to high and low nicotine cigarettes, *British Medical Journal* 1973;4:512-516. *See* AR (Vol. 89 Ref. 485).

Gori G, Low risk cigarettes: a prescription, *Science* 1976;94(4271):1243-1246. *See* AR (Vol. 535 Ref. 96, vol. IV.D, at 1-5).

[688] Department of Health and Human Services, *The Health Consequences of Smoking: The Changing Cigarette, A Report of the Surgeon General, 1981*, at 98 (citation omitted). *See* AR (Vol. 123 Ref. 1586).

4. The Cigarette Manufacturers Design Commercially Marketed Cigarettes to Provide a Pharmacologically Active Dose of Nicotine

The evidence summarized in section II.C.3. that the manufacturers have conducted product research and development to establish the doses of nicotine needed to produce pharmacological effects and to optimize nicotine deliveries to consumers establishes that the manufacturers have the capacity to design cigarettes that provide pharmacologically active doses of nicotine. In this section, the Agency evaluates the evidence in the record regarding the manipulation and control of nicotine in commercial cigarettes.[689]

As discussed below, the evidence in the administrative record establishes that many of the product research and development efforts described in section II.C.3. are used in important ways in the commercial cigarettes marketed today. The available evidence shows that the cigarette manufacturers pay careful attention to nicotine in all phases of cigarette manufacture. As described in the Jurisdictional Analysis, the focus on nicotine is apparent at each step—from the growing and purchasing of tobacco leaves, to the blending of different tobacco varieties, to the design and manufacture of the finished cigarette. *See* 60 FR 41693–41733.

The evidence in the record further demonstrates that the final products—the finished cigarettes sold to consumers—reflect the manufacturers' careful attention to

[689] The evidence in section II.C.2., supported by the evidence in section II.C.3. that the manufacturers "have in mind" that these products will have and be used for pharmacological effects, is sufficient by itself to establish intended pharmacological use. It is thus not necessary for the Agency to establish that commercial cigarettes have been affirmatively designed to provide a pharmacologically active dose of nicotine to show that the manufacturers "intend" the pharmacological effects and uses of cigarettes. For example, a manufacturer of a traditional full-strength cigarette may not need to take any specific design steps to insure that the cigarette provides a pharmacologically active dose of nicotine. Nevertheless, this manufacturer's understanding and expectation that the full-strength cigarette will be used by consumers for drug purposes would be sufficient to establish the cigarette's intended pharmacological use.

nicotine. Manufacturers of commercially marketed cigarettes commonly manipulate nicotine deliveries to provide remarkably precise, pharmacologically active doses of nicotine to consumers. The principal techniques that are used to control and manipulate nicotine deliveries include: (1) the use of nicotine-rich tobacco blends in low-tar cigarettes; (2) the use of filtration and ventilation technologies that selectively remove more tar from smoke than nicotine; and (3) the use of chemical additives that increase the percentage of "free" nicotine in cigarette smoke. Control is also achieved as a result of extensive attention to nicotine in tobacco breeding, leaf purchasing, leaf blending, and the manufacture of reconstituted tobacco.

Indeed, the evidence in the record establishes that cigarette designs in recent decades have been driven by the manufacturers' desire to maintain nicotine deliveries at pharmacologically active levels. As consumer awareness of the health effects of smoking has increased, the cigarette manufacturers have responded by adding filters and using ventilation to reduce tar deliveries. However, the manufacturers have not reduced nicotine deliveries proportionately. Rather, the evidence available to the Agency indicates that they have strived to ensure that nicotine deliveries remain at a pharmacologically active level.[690]

a. The Manufacturers Use Nicotine-Rich Tobacco Blends in Low-Tar Cigarettes

Perhaps the clearest example of deliberate manipulation and control to maintain nicotine deliveries at levels sufficient to provide pharmacological satisfaction occurs in the

[690] RJR's Eclipse, the new tobacco product that is being test-marketed, carries this effort to close to its logical conclusion—maintaining nicotine deliveries at the level of conventional ultra-low-tar cigarettes while allegedly reducing many of the tar components of tobacco smoke substantially below these levels. Eclipse is discussed further in section II.C.3.b., above (product research and development).

manufacture of low-tar cigarettes. The evidence in the administrative record indicates that cigarette manufacturers commonly use nicotine-rich tobacco blends in these products. Approximately 80% of the cigarettes on the market today are either low-tar (6 to 15 mg tar) or ultra-low-tar (less than 6 mg tar).[691]

i. The Use of Nicotine-Rich Tobacco Blends in the 1950's. The evidence in the record indicates that the use of richer nicotine blends first occurred in the 1950's, when filters were first added to cigarettes. Documents provided to the Agency by the tobacco industry show that a shift to higher nicotine blends occurred to offset the reductions in nicotine deliveries caused by the use of filters. According to one 1956 document: "*With the increase in production of filter tip cigarettes, . . . demand has increased for heavier-bodied [tobacco] types that have* full aroma and flavor and *a relatively high nicotine content.*"[692]

As early as 1957, the U.S. Department of Agriculture (USDA) recognized that the introduction of filters was causing increased demand for higher nicotine tobacco. That year, the director of the tobacco division of USDA's Agricultural Marketing Service, Stephen E. Wrather, testified before Congress that the industry had "moved up the stalk"

[691] Federal Trade Commission, *Report of "Tar," Nicotine, and Carbon Monoxide of the Smoke of 1107 Varieties of Domestic Cigarettes* (1995). *See* AR (Vol. 535 Ref. 96, vol. IV.B).

[692] Jones GL, Collins WK, *Measured Crop Performance Tobacco 1956*, Department of Field Crops, N.C., State College, Raleigh N.C., Research Report No. 4 (Dec. 1956), at 1 (emphasis added). *See* AR (Vol. 535 Ref. 96, vol. IV.K).

in blending tobacco for use in filter cigarettes.[693] "Moving up the stalk" is a reference to the higher nicotine content in the upper leaves of tobacco plants.[694]

Wrather also indicated that using this higher nicotine tobacco in the blend for filtered cigarettes enabled manufacturers to maintain the same "strength" levels in the smoke that existed in unfiltered cigarettes.[695] A 1957 *Consumer Reports* analysis of nicotine levels in filtered and unfiltered cigarettes placed in the record of the hearing showed that the average nicotine content in regular-size cigarettes with filters was higher than in regular-size cigarettes without filters.[696] This could only have been accomplished through the use of higher nicotine tobacco leaves in the blend for filtered cigarettes.

ii. The Use of Nicotine-Rich Tobacco Blends Today. During the 1960's and 1970's, the demand of consumers for "healthier" cigarettes led to further declines in tar yields. As described above in section II.C.3., this caused the cigarette manufacturers to develop methods to ensure that the nicotine levels in cigarettes did not drop below acceptable levels.[697]

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[693] *False and Misleading Advertising (Filter-tip Cigarettes): Hearings Before the Subcommittee of the Committee on Government Operations, U.S. House of Representatives*, 85th Cong., 1st Sess. 189 (1957) (testimony of Stephen E. Wrather). *See* AR (Vol. 172, Ref. 2035).

[694] *See, e.g.*, Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 10 ("Higher stalk tobacco leaves do have more nicotine than lower stalk leaves on the same plant"). *See* AR (Vol. 529 Ref. 104).

[695] *False and Misleading Advertising (Filter-tip Cigarettes): Hearings Before the Subcommittee of the Committee on Government Operations, U.S. House of Representatives*, 85th Cong., 1st Sess. 196 (1957) (testimony of Stephen E. Wrather). *See* AR (Vol. 172, Ref. 2035).

[696] *Id.* at 662 (exhibit 15c).

[697] Philip Morris USA, Research and Development Five Year Plan, 1974-1978 (May 1973), in 141 Cong. Rec. H8130-8131 (daily ed. Aug. 1, 1995). *See* AR (Vol. 711 Ref. 6).

See also Low Delivery Cigarettes and Increased Nicotine/Tar Ratios, A Replication (Oct. 1975), in 141 Cong. Rec. H8009 (daily ed. Jul. 31, 1995). *See* AR (Vol. 27 Ref. 376a).

The evidence in the record indicates that the low-tar cigarettes on the market today reflect the industry's concerns with providing an acceptable nicotine level. As numerous documents in the record reveal, low-tar cigarettes are specifically blended to increase their nicotine concentrations. For instance, the administrative record includes the following descriptions of the use of blending to control and manipulate nicotine:

- William Farone, the former director of applied research at Philip Morris, stated that "[t]he industry employs two principal means of controlling the nicotine levels."[698] One of these is "*modification and control of the tobacco blend*, i.e., the ratio of Burley (air-cured), Bright (flue-cured), Oriental, stems, expanded tobacco products, and reprocessed tobacco products such as tobacco sheet made from stems and waste leaf."[699] According to Farone:

> *Product developers and blend and leaf specialists were responsible for manipulating and controlling the design and production of cigarettes in order to satisfy the consumer's need for nicotine in lower yield products.*
>
> *Blend changes were an especially important tool used to ensure desired nicotine levels.* Tar is a function of tobacco weight. However, an all-burley cigarette will produce a higher nicotine level than an all-bright cigarette of the same weight. The industry knew that by using a higher percentage of higher nicotine tobacco in their low tar cigarettes they could achieve an increase of their nicotine levels.[700]

Jones B, Houck W, Martin P (Philip Morris Inc.), *Low Delivery Cigarettes and Increased Nicotine/Tar Ratios, A Replication* (Oct. 1975), in 141 Cong. Rec. H8132 (daily ed. Aug. 1, 1995). *See* AR (Vol. 711 Ref. 6).

Wood DJ, Wilkes EB (BATCO), *Project Wheat - Part 2: U.K. Male Smokers: Their Reactions to Cigarettes of Different Nicotine Delivery as Influenced by Inner Need* (Jan. 30, 1976), at 2. *See* AR (Vol. 20 Ref. 204-2).

[698] Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 5. *See* AR (Vol. 638 Ref. 2).

[699] *Id.* at 5 (emphasis added).

[700] *Id.* at 10 (emphasis added).

- Ian Uydess, the former Philip Morris scientist, stated that:

> Nicotine levels were routinely targeted and adjusted by Philip Morris in its various products at least in part, through blend changes . . . .
>
> . . . .
>
> When Philip Morris designed a new or modified blend, they used their stored tobacco inventories much like a scientist would use a chemical stockroom to select the ingredients needed to synthesize a new material. . . .
>
> *. . .Philip Morris routinely applied this knowledge of selective tobacco blending to achieve desired nicotine . . . levels in the products that it designed and marketed.*[701]

- Alexander Spears, the vice chairman and chief operating officer of Lorillard Tobacco Co., wrote that "*the lowest 'tar' segment is composed of cigarettes utilizing a tobacco blend which is significantly higher in nicotine.*"[702] According to Spears, the nicotine concentration in the lowest tar cigarettes in 1981 was 22% greater than the concentration in regular cigarettes (2.2% versus 1.8%).[703] Spears further explains that "[h]igher nicotine levels can be achieved by decreasing Oriental and the stem and tobacco sheet and increasing the Burley and upper stalk positions of both the flue-cured and the Burley tobacco."[704]

- Another Lorillard researcher, Vello Norman, has explained that the shift to tobacco blends with more nicotine-rich burley tobacco was motivated by a desire "to impart

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[701] Declaration of Uydess IL (Feb. 29, 1996), at 8, 10 (emphasis added). *See* AR (Vol. 638 Ref. 1).

[702] Spears AW, Jones ST (Lorillard Tobacco Co.), Chemical and Physical Criteria for Tobacco Leaf of Modern Day Cigarettes, *Recent Advances in Tobacco Science*, Oct. 6-9, 1981;7:19, at 22 (emphasis added). *See* AR (Vol. 26 Ref. 373).

[703] *Id.* at 21.

[704] *Id.* at 24.

more impact to smoke" to offset the effects of "gradually lower cigarette smoke yields":

> As various means were used to gradually lower cigarette smoke yields there has been a tendency to use more Burley in order to impart more impact to smoke. Thus, while total smoke yields of cigarettes have diminished, the relative composition of smoke has, in the case of many cigarettes, shifted slightly towards what is more characteristic of Burley.[705]

"Impact" is a term used by the tobacco industry to describe effects that are associated with nicotine delivery. *See, e.g.,* Jurisdictional Analysis, 60 FR 41776–41777.

- Similarly, a scientist at Brown & Williamson reported that "*[u]ltra low tar cigarettes . . . use blends which contain about 20% more nicotine.*"[706]

Brown & Williamson's development of the high-nicotine Y-1 variety of tobacco, which is discussed above in section II.C.3.c.iii., was an attempt to use breeding and blending to increase nicotine concentrations in low-tar cigarettes. An example in which blending has been used to increase nicotine concentrations in commercial low-tar cigarettes is Philip Morris' Merit cigarettes. FDA has analyzed the relative nicotine concentrations in the regular, low-tar, and ultra-low-tar versions of Merit cigarettes. FDA's analysis revealed that Merit Filter 100's contained 1.46% nicotine, but that Merit Ultra Lights 100's contained 1.67% nicotine, and Merit Ultima 100's (the lowest-tar product) contained 1.99% nicotine. *See* 60 FR 41723–41724. These findings, which

[705] Norman V (Lorillard Research Center), *Changes in Smoke Chemistry of Modern Day Cigarettes*, Greensboro, NC (1982), at 168. *See* AR (Vol. 99 Ref. 813).

[706] Reynolds ML (Brown & Williamson), *Symposium Summary*, presented at Winston Salem, NC, at 179 (Oct. 6-9, 1981) (emphasis added). *See* AR (Vol. 99 Ref. 823).

show nicotine concentrations increasing as reported tar yields drop, are unchallenged by Philip Morris.

A similar pattern of higher nicotine concentrations in lower tar products exists in other brands. For instance, in 1981, Brown & Williamson launched a new ultra-low-tar brand called Barclay. Tests of Barclay and fourteen other cigarettes in 1982 showed that the tobacco in the Barclay blend had a nicotine concentration of 2.69%—higher than any other brand tested. In fact, Barclay's nicotine concentration was over 90% higher than the regular-strength Lucky Strike cigarette tested.[707] Other brands show the same pattern of higher nicotine concentrations in the lowest-tar cigarettes.

These industry blending practices facilitate the use of low-tar products for pharmaceutical purposes. The enhanced nicotine concentrations in the lowest tar cigarettes result in higher nicotine deliveries than would otherwise occur, allowing consumers to more readily satisfy their addiction to nicotine and obtain other pharmacological effects of nicotine from low-tar cigarettes.

iii. The Use of Nicotine-Rich Tobacco Blends Is Not Due to Accident or Taste. In the Jurisdictional Analysis, FDA summarized the evidence then available to the Agency regarding the use of nicotine-rich blends in low-tar cigarettes, concluding that "[s]ignificant evidence also demonstrates that tobacco manufacturers have used blending techniques to increase nicotine concentrations in low-tar cigarettes and thereby maintain nicotine delivery while reducing tar delivery." 60 FR 41708. The public comment period

[707] *Regulation of Tobacco Products (Part 3): Hearings Before the Subcommittee on Health and the Environment, House Energy and Commerce Committee, U.S. House of Representatives*, 103d Cong., 2d Sess. 173 (Jun. 23, 1994). *See* AR (Vol. 709 Ref. 3).

provided the cigarette manufacturers with an opportunity to provide an alternative explanation of this evidence of nicotine manipulation. As explained below, however, the industry does not effectively rebut the evidence that the manufacturers use nicotine-rich blends to enhance nicotine deliveries. The industry's failure to provide a convincing counter-explanation for its actions is further support for the Agency's finding that the manufacturers design low-tar cigarettes with nicotine-rich blends to maintain adequate nicotine deliveries.

The cigarette manufacturers make two conflicting arguments in response to the evidence that they manipulate tobacco blends to enhance nicotine content in low-tar products. First, they categorically assert that they "do not independently 'control' for or 'manipulate' the nicotine content in any of their blends."[708]

Second, they maintain that, to the extent they do control and manipulate nicotine content, they do so strictly for taste. Thus, they contend that (1) they "blend their tobaccos for flavor"[709] and (2) "nicotine plays an important role in the taste and flavor of cigarette smoke."[710] During his appearance before Congress, for instance, William Campbell, the president of Philip Morris, conceded that the ultra-light Merit Ultima cigarette uses a tobacco blend with a higher concentration of nicotine than the regular Merit cigarette, but insisted that "it's there for taste."[711] Similarly, Thomas Sandefur, then

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[708] Joint Comment of Cigarette Manufacturers (Jan. 2, 1996), Vol. IV, at 66. *See* AR (Vol. 535 Ref. 96).

[709] *Id.*

[710] R.J. Reynolds Tobacco Co., Comment (Jan. 2, 1996), at 50. *See* AR (Vol. 519 Ref. 103).

[711] *Regulation of Tobacco Products (Part 1): Hearings Before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 764 (Apr. 14, 1994) (testimony of W.I. Campbell). *See* AR (Vol. 707 Ref. 1).